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TDANOBALTTAL			Application Number		10/533,764	
TRANSMI			Filing Date		May 4, 200	05
FOR	VI		First Named Invent	or	William Bro	own
			Art Unit		To Be Determined	
(to be used for all correspond	ence after ini	itial filing)	Examiner Name		To Be Dete	ermined
Total Number of Pages in This	Submissio	n	Attorney Docket Nu	ımber	ASZN0036	5-100 (100884-1P US)
		ENCLO	SURES (check all tha	t apply)		
☐ Fee Transmittal Form		Drawing(s	6)		After Allowanc	e Communication to TC
Fee Attached		Licensing	-related Papers			unication to Board d Interferences
Amendment / Reply		Petition				unication to TC Brief, Reply Brief)
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Affidavits/declaration(	(s)		Attorney, Revocation of Correspondence		Status Letter	
Extension of Time Reque	st	Terminal I	Disclaimer		Other Enclosure(s) (please identify below):	
Express Abandonment Ro	equest	Request for Refund  CD, Number of CD(s)		pp.);	Form PTO SB/08a (6 pp.); Form PTO SB/08b (3 pp.); (66) References Cited, (52) References Enclosed.	
☐ Information Disclosure St	atement	☐ Landscape Table on CD			0364.	
Certified Copy of Priority Document(s)		Remarks				
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	SIGN	ATURE OF	APPLICANT, ATTOR	RNEY, O	R AGENT	
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Signature		Port	e Change			
Printed Name Paul K. Legaar		d, Ph.D.			·	
Date	rember Loop	Reg. No.	38,534			
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	age as first	t class mail i	in an envelope addres			with the United States Postal for Patents, P.O. Box 1450,
Signature	12	OK I	Lan 0			
Typed or printed name	Paul K. Le	gaard, Ph.D.,	Registration No. 38,534		Date	30 NOVENSOR ZOOT

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Brown and Griffin

Serial No.: 10/533,764

Art Unit: To Be Determined

Filing Date: May 4, 2005

**Examiner: To Be Determined** 

For: 4(PHENYL-PIPERAZINYL-METHYL) BENZAMIDE DERIVATIVES AND THEIR USE FOR THE TREATMENT OF PAIN OR GASTROINESTINAL

**DISORDERS** 

I certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA, 22313-1450.

on 30 Notember 2005

Paul K. Legaard, Ph.D., Registration No. 38,534

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

## INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Forms SB/08A and SB/08B, formerly known as PTO Form 1449, submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

## This Information Disclosure Statement is being filed:

	within three months of the filing date of the patent application.
	within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
$\boxtimes$	before the mailing date of a first Office Action on the merits.

		the mailing date of a first Office Action on the merits after the filing of lest for Continued Examination under § 1.114.
	of a Red	he mailing date of a first Office Action on the merits or after the filing equest for Continued Examination under § 1.114, but before the mailing f a Final Office Action under 37 C.F.R. § 1.116 or a Notice of ance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
		the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
		or
		the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
		No fee is owed by the applicant(s).
	Statem Final S C.F.R.	cordance with 37 C.F.R. § 1.129(a), this Information Disclosure tent is being filed in connection with the first or second After Submission, and accordingly is accompanied by the Statement under 37 § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in I.R. § 1.17(p), is attached.
	Notice with, t	the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously the payment of the Issue Fee, and accordingly is accompanied by the nent under 37 C.F.R. § 1.97(e), and the Fee of \$180.00 set forth in 37 §1.17(p).
$\boxtimes$		s of the Reference Citations (excluding the U.S. Patent Documents) on the attached PTO Forms SB08/A and SB/08B are enclosed herewith.
	EXCE	CPT THAT:
		In view of the voluminous nature of Reference Citation AE, and the likelihood that this reference are available to the Examiner, a copy is not enclosed herewith.
		In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
		If the foregoing publication is not available to the Examiner, Applicants will endeavor to supply a copy at the Examiner's request.

Sta	tement under 37 C.F.R. § 1.97(e)	•
	in the Information Disclosure State foreign patent office in a counterp	states that each item information contained ement was cited in a communication from a art foreign patent application not more than he Information Disclosure Statement.
Sta	tement under 37 C.F.R. § 1.704(d)	
	The undersigned attorney hereby s contained in the Information Discle communication from a foreign pate the communication was not receive in §1.56(c) more than 30 days prio Disclosure Statement.	osure Statement was cited in a ent office in a counterpart application and ed by any individual designated
Fee	es	
$\boxtimes$	No Fee is owed by the applicant(s)	
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	The Petition Fee of \$130.00 under	37 C.F.R. § 1.17(i)(1) is enclosed herewith.
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$\boxtimes$	Please charge any deficiency or c 50-1275.	redit any overpayment to Deposit Account
	No fee or Statement is required un-	der 37 C.F.R. § 1.97(b).
		Respectfully submitted,
		Preklo
Dated: 38	NOVEMBER 2005	Paul K. Legaard, Ph.D. Registration No. 38,534

COZEN O'CONNOR, P.C. 1900 Market Street, 5<sup>th</sup> Floor Philadelphia, PA 19103-3508 (215) 665-2000 – Telephone (215) 665-2013 - Facsimile

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	Substitute for form 1449A/PTO			Complete if Known		
				Application Number	10/533,764	
	INFORMATION DISC	CLC	SURE	Filing Date	May 4, 2005	
	STATEMENT BY AF	PL	CANT	First Named Inventor	William Brown	
				Art Unit	To Be Determined	
	(Use as many sheets as ned	essary	)	Examiner Name	To Be Determined	
Shee	t 1	of_	6	Attorney Docket Number	ASZN0036-100 (100884-19 US	

**U. S. PATENT DOCUMENTS Document Number Publication Date** Name of Patentee or Pages, Columns, Lines, Where Examiner MM-DD-YYYY Initials\* Applicant of Cited Document Relevant Passages or Relevant Number-Kind Code<sup>2 (# known)</sup> Figures Appear 3,940,386 A1 02/24/1976 Szabo et al. US-11/12/1996 A2 5,574,159 Chang et al. US-Α3 5,681,830 10/28/1997 Chang et al. US-09/15/1998 Chang et al. A4 5,807,858 US-**A5** 5,854,249 12/29/1998 Chang et al. US-6,130,222 10/10/2000 Roberts et al. A6 US-<u>A7</u> 6,680,318 01/20/2004 Brown et al. US-**A8** 6,680,321 01/20/2004 Roberts et al US-**A9** 6,696,447 02/24/2004 Brown et al. US-08/31/2004 A10 6,784,181 Brown et al. US-10/533,654 A11 05/04/2005 Brown et al US-A12 10/533,744 05/04/2005 Brown et al. US-A13 10/714,447 11/17/2003 Roberts et al. A14 10/477,642 11/13/2003 Brown et al. US-US-US US-

			FOREIG	N PATENT DOCL	JMENTS		
Examiner	Cite		Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines,	-6
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	В1	WO	86/04584	08/14/1986	Aktiebolaget Leo		
	B2	WO	91/07967	06/13/1991	Janssen		
	В3	wo	01/74805	10/11/2001	AstraZeneca AB		
	B4	wo	93/15062	08/05/1993	The Wellcome		
	B5	wo	97/23466	07/03/1997	Astra Pharma Inc.		

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Complete if Known Substitute for form 1449A/PTO **Application Number** 10/533,764 Filing Date INFORMATION DISCLOSURE May 4, 2005 First Named Inventor STATEMENT BY APPLICANT William Brown Art Unit To Be Determined **Examiner Name** (Use as many sheets as necessary) <u>To Be Determined</u> Attorney Docket Number 6 ASZN0036-100 (100884-1P

U. S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant		
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Initials*	No.¹	Country Co	ode <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> ( <i>if known</i> )	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T⁵
	В6	wo	95/04051	02/09/1995	The Wellcome		
	В7	wo	98/28270	07/02/1998	Astra Aktiebolag		
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***************************************	В9	wo	99/33806	07/08/1999	Ortho-McNeil		
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Sheet	3	of	6	Attorney Docket Number	ASZN0036-100 (100884-1P )

U. S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
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	B11	EP	0283310	09/21/1988	Sankyo Company						
	B12	EP	0166302	01/02/1986	Polindustria						
	B13	EP	0133323	02/20/1985	The Wellcome						
	B14	GB	2210366	06/07/1989	American Home						
	B15	GB	2076403	12/02/1981	Selvi & C.S.p.A.						

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Complete if Known Substitute for form 1449A/PTO Application Number 10/533,764 Filing Date May 4, 2005 INFORMATION DISCLOSURE First Named Inventor STATEMENT BY APPLICANT William Brown Art Unit To Be Determined **Examiner Name** To Be Determined (Use as many sheets as necessary) **Attorney Docket Number** 6 ASZN0036-100 (100884-1P

Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where	
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Initials*	No.'	No. 1 Country Code <sup>3</sup> Number <sup>4</sup> 'Kind Code <sup>5</sup> ( <i>if known</i> )		MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	L™				
	B16	FR	2696744	04/15/1994	Laboratoires						
	B17	DE	2431178	01/16/1975	Cermol S.A.		Г				
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	B22	EP	0624584	08/19/1998	Daiichi	***************************************					
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Su	bstitute for form 1449A/PTO			Complete if Known		
				Application Number	10/533,764	
]]	NFORMATION DIS	CLC	SURE	Filing Date	May 4, 2005	
S	STATEMENT BY A	PL	CANT	First Named Inventor	William Brown	
				Art Unit	To Be Determined	
	(Use as many sheets as ne	cessary	)	Examiner Name	To Be Determined	
Sheet	6	of	6	Attorney Docket Number	ASZN0036-100 (100884-1P VS	

Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where	
Initials*	No.1	Number-Kind Code <sup>2 (d known)</sup>	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	
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	FOREIGN PATENT DOCUMENTS										
Examiner	Cite		Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines,					
Initials*	No.1	Country Co	ode <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T°				
	B26	WO	2005/066148	07/21/2005	AstraZeneca AB		Π				
	B27	WO	2004/041801	05/21/2004	AstraZeneca AB		Г				
	B28	WO	2004/041800	05/21/2004	AstraZeneca AB		П				
	B29	WO	03/029215	04/10/2003	AstraZeneca AB	***************************************					
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Examiner		 Date		 
Signature		Considere	1	

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	Substitute for	form 1449B/PTO				Complete if Known
					Application Number	10/533,764
	INFOF	RMATION DI	SCLO	SURE	Filing Date	May 4, 2005
STATEMENT BY APPLICANT					First Named Inventor	William Brown
					Art Unit	To Be Determined
		(Use as many sheets as	necessary,	)	Examiner Name	To Be Determined
$\overline{\ }$	Sheet	1	of	1	Attorney Docket Number	ASZN0036-100 (100884-1P US)

	NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²					
	C1	Bilsky et al., "SNC 80, A Selective, Nonpeptidic and Systemically Active Opioid Delta Agonist," J. Pharmacol. Experi. Ther. 273:359-366 (1995)						
	C2	Takemori et al., "Selective Natrexone-Drived Opioid Receptor Antagonists," Annu. Rev. Pharmacol. Toxicol. 32:239-269 (1992)						
•••••	С3	Bilsky et al., "Characterization of Enantiomers of (+) BW373U86 and Related Compounds: Highly Selective Non-Peptidic Delta Opioid Agonists," Reg. Peptides 54:25-26 (1994)						
	C4	Calderon et al., "Probes for Narcotic Receptor Mediated Phenomena. 19. Synthesis of Opioid Receptor Agonist," J. Med. Chem. 37:2125-2128 (1994)						
	C5	Calderon et al., "Probes for Narcotic Receptor Mediated Phenomena. 23. Synthesis Opioid Receptor Ligands," J. Med. Chem. 40:695-704 (1997)						
	С6	Chang et al., "A Novel, Potent and Selective Nonpeptidic Delta Opioid Receptor Agonist BW373U86," J. Pharmacol. Exper. Therap. 267:852-857 (1993)						
	С7	Katrizky et al., "Benzotriazole-Mediated Arylalkylation and Heteroarylalkylation," Chem. Soc. Rev. 23:363-373 (1994)						
	С8	Kingsbury et al., "Synthesis of Structural Analogs of Leukotriene B and their Receptor Binding Activity," J. Med. Chem. 36:3308-3320 (1993)						
•••••	C9	Lopez et al., "Exploring the Structure-Activity Relationships Opioid Receptor Nonpeptide Agonist Ligand," J. Med. Chem. 42:5359-5368 (1999)						
<b></b>	C10	Plobeck et al., "New Diarylmethylpiperazines as Potent and Selective Nonpeptidic Opioid Receptor Agonists with Increased In Vitro Metabolic Stability," J. Med. Chem. 43:3878-3894 (2000)						

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Signature	Considered	

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STATEMENT BY APPLICANT				CANT	First Named Inventor	William Brown	
					Art Unit	To Be Determined	
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	Sheet	1	of	1	Attorney Docket Number	ASZN0036-100 (100884-1P US)	

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²					
	C11	Suggs et al., "Facile Synthesis fo 8-Substituted Quinolines," J. Org. Chem., 45:1514-1515 (1980)						
	C12	Zhang et al., "Probes for Narcotic Receptor Mediated Phenomena. 26. Synthesis Opioid Receptor Ligands," J. Med. Chem. 42:5455-5463 (1999)						
	C13	English Abstract for Reference B16 on PTO/SB/08A, Page 4						
	C14	English Abstract for Reference B17 on PTO/SB/08A, Page 4						
	C15	English Abstract for Reference B18 on PTO/SB/08A, Page 4						
	C16	English Abstract for Reference B19 on PTO/SB/08A, Page 4						
	C17	Burkey et al., "The Efficacy of Delta-Opioid Receptor-Selective Drugs," Medline Abstract for Life Sci. 62:1531-1536 (1998)						
	C18	Nagase et al., "The Pharmacological Profile of Delta Opioid Receptor Ligands, (+) and (-) TAN-67 on Pain Modulation," Medline Abstract for Life Sci. 68:2227-2231 (2001)						
•	C19	Green, "Protective Groups in Organic Synthesis," pgs. 267-268 and 331 (1981)						
	C20	Abstract for HU 217619. A corresponding English language PCT application is cited as Reference B1 listed on PTO/SB/08A, Page 1						

E	xaminer	Date	
l s	ignature	Considered	

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•	Substitute fo	or form 1449B/PTO			Complete if Known		
					Application Number	10/533,764	
	INFO	RMATION DI	SCLO	SURE	Filing Date	May 4, 2005	
	STATEMENT BY APPLICANT				First Named Inventor	William Brown	
					Art Unit	To Be Determined	
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	Sheet	1	of	1	Attorney Docket Number	ASZN0036-100 (100884-1P US)	

NON PATENT LITERATURE DOCUMENTS								
Examiner Initials*								
	C21	Abstract for HU 215847. A corresponding English language PCT application is cited as reference B2 on PTO/SB/08A, Page 1						
	C22	Nortey et al., "Piperazinyl Benzamidines: Synthesis and Affinity for the Delta Opioid Receptor," Bioorganic & Medicinal Chemistry Letters, Vol. 11, pgs. 1741-1743 (2001)						
	C23	Snyder et al., "Historical Review: Opioid Receptors," Trends in Pharmacological Sciences, Vol. 24, pgs. 198-205 (2003)						
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